AMAREX JOB DESCRIPTION

Position Title: **Senior Regulatory and Scientific Analyst**	**Department: Regulatory Affairs**
Reporting Requirements: Reports to Head of Regulatory Affairs	**Supervisory Responsibilities: None**
FLSA Status: Exempt	**Travel Requirements: < 10%**

POSITION SUMMARY:

The Regulatory and Scientific Analyst assists and coordinates activities regarding submission of regulatory documents to and interactions with FDA, IRBs and other regulatory governing bodies. Other responsibilities may include review of regulatory interpretations, and updating the company-wide regulatory library.

RESPONSIBILITIES:

- Preparation, compilation and review of regulatory documents.
- Assist in preparation for FDA meetings.
- Assist in preparation of minutes of client meetings.
- Monitoring time-line adherence of ongoing regulatory activities and creation-maintenance of a calendar of regulatory activities.
- Creation, implementation, formatting, publishing, and maintenance of the regulatory submission master files and database to capture the history of each product line and ease of data retrieval for domestic and international product approvals.
- Assist in preparation of numerous communications; including memos, correspondence, SOPs, guidelines and presentations.
- Maintain current regulatory knowledge of international and domestic regulations, guidelines, and standards and apply appropriate implementation strategies.
- Other duties as assigned.

REQUIRED EDUCATION, QUALIFICATIONS AND EXPERIENCE:

- Master's degree and 1-2 years of related experience or equivalent education and experience.
- Strong verbal and written communication skills.
- Proficient in MS Office software.
- Detail-oriented with excellent follow-up skills.
- Ability to work independently with minimal supervision.
- Effective interpersonal skills, including the ability to work in a team environment,contributing to a collaborative work atmosphere.